K043019

DEC - 1 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Injection Kit

Product Trade Name: Vascular Solutions Sclero-Kit

Classification Name: Unclassified
Product Code: FMF, FMI, FPA

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369

Establishment Registration: 2134812

Contact: Sara L. Coon
Senior Regulatory Affairs Associate
(763) 656-4300 phone
(763) 656-4200 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:
Each kit is provided sterile and contains disposable 10ml syringe, 3ml syringe with needle, butterfly needle with attached extension tubing and syringe connector.

Intended Use:
The Vascular Solutions Sclero-Kit is indicated for delivery of sclerosing agents. Sclerosing agents may be used for treatment of small uncomplicated varicosities of the lower extremities that show simple dilation with competent valves.

Summary of Non-Clinical Testing:

Testing conducted included assessments of the design verification of the Sclero-Kit along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Sclero-Kit for its intended use.

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Summary of Clinical Testing:

No clinical evaluations of this product have been conducted.

Predicate Devices:

The VSI Sclero-Kit is a kit of routinely used medical components that have been combined and sterilized for the convenience of the end user for use in the treatment of small uncomplicated varicosities. The kit components are equivalent to the predicate needle and syringe devices. This combination of devices is commonly combined for use in the treatment varicosities as described in the current medical textbooks and literature.

Conclusions:

The Sclero-Kit is substantially equivalent to the predicate needle and syringe devices. The testing performed confirms that the Sclero-Kit will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Sara L. Coon
Senior Regulatory Affairs Associate
Vascular Solutions, Incorporated
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K043019
Trade/Device Name: Vascular Solutions Sclero-Kit
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 2, 2004
Received: November 3, 2004

Dear Ms. Coon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

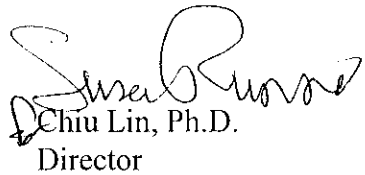
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K043019

Device Name: Vascular Solutions Sclero-Kit

Indications for Use:

The Vascular Solutions Sclero-Kit is indicated for delivery of sclerosing agents. Sclerosing agents may be used for treatment of small uncomplicated varicosities of the lower extremities that show simple dilation with competent valves.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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